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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: First Amendment Comments, Docket 02N-0209

To Whom it May Concern:

Hill's Pet Nutrition ("Hill's") is submitting these comments to the Food and Drug Administration ("FDA") in response to the Notice "Request for Comment on First Amendment Issues," 67 Fed. Reg. 34942 (May 16, 2002) ("Notice"). In the Notice, FDA solicits comments about the compliance of the agency's regulations, guidances, policies and practices with the First Amendment to the U.S. Constitution and related case law. The elements of the Notice most relevant to Hill's and the pet food industry inquire as to whether FDA's speech-related regulations and policies advance the health concerns they are designed to address and whether they unconstitutionally burden free speech under the First Amendment.

1. Introduction

Hill's believes that, while FDA's policies are generally consistent with the First Amendment and related case law, there are areas related to pet foods where modification is needed in order to be less restrictive of commercial speech. Specifically, Hill's urges FDA's Center for Veterinary Medicine ("CVM") to modify its positions to: (1) allow structure/function claims for all safe and substantiated ingredients in pet foods; (2) allow for a greater range of claims to communicate the nutritional benefits of veterinary medical foods to pet owners; and (3) allow use of qualified claims to ensure consumers receive truthful and non-misleading information.

Hill's is the manufacturer and distributor of the leading Science Diet® and Prescription Diet® pet foods. Hill's mission is to provide the best, leading-edge pet nutrition, technology, products, and expertise to pet owners, veterinary professionals, and pet specialty retailers worldwide.

Pet food has become a significant market category and merits close attention by FDA. Currently an 11 billion dollar industry, the pet food market

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experienced a 3.1% growth rate between 1999 and 2000.[1] Moreover, as of 2000 nearly 38% of all U.S. households had one or more dogs, while 34% of all Americans have at least one cat in their home. The latest statistics show that this rate of pet ownership increased by almost 2 percent between 1999 and 2000 and continues to grow.[2] As pets occupy an ever more central role in the lives of Americans, concern for the health and well being of those animals has increased, and pet owners are more than ever looking for information about how products can sustain their pets' lives.

Hill's appreciates the opportunity to comment on First Amendment issues. With the recent Thompson v. Western States Medical Center, 535 U.S. ___ (April 29, 2002), Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) and Washington Legal Foundation v. Henney, 13 F. Supp.2d 51 (D.D.C. 1998) decisions, Hill's believes that FDA's request for comments on this issue is timely. Moreover, First Amendment issues are critical for Hill's which aims to accurately communicate the health benefits of its scientifically formulated products to pet owners.

Hill's believes FDA should take the lead among regulators of pet food and modify its positions on structure/function claims, claims for veterinary medical foods made direct to consumers, and the use of qualified claims on pet foods, so that pet food companies can effectively communicate information about important health benefits.

2. Protection of Commercial Speech by the First Amendment

As outlined by the courts, the First Amendment mandates that government schemes regulating commercial speech pass a three-part test. In brief, the first requirement is that the asserted government interest be substantial. Second, the government regulation must *directly* advance the governmental interest asserted; and third, there must be a reasonable fit between the government interest and the means chosen to accomplish it. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980). Government regulations that do not meet this test may be in violation of the commercial speech aspect of the First Amendment.

Three recent judicial decisions have applied these principles to FDA regulatory schemes. Collectively, these cases establish that under the First Amendment parties may not be required to obtain government assent prior to engaging in truthful, non-misleading speech about lawful activities.

Thompson v. Western States Medical Center, 535 U.S. ___ (April 29, 2002), the most recent case, established that a ban on advertising drug compounding services under the Food and Drug Administration Modernization Act ("FDAMA") violated the First Amendment right to commercial speech as articulated in Central Hudson. The Supreme Court found that, even assuming that the ban on advertising directly advanced the government's interest in preventing compounding

[1] Pet Food Institute 2001.
[2] Pet Food Institute 2001.

operations from manufacturing large quantities of "new drugs," the government had failed to demonstrate that the restrictions on speech were not more extensive than necessary to serve those interests. The Court found that there were non-speech related means, such as regulating large-scale manufacturing, prohibiting wholesale sale, or limiting manufacturing to prescriptions received to achieve the government's goal of preventing compounding operations from attracting a large-scale market.

In Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), a dietary supplement manufacturer challenged FDA's rejection of four proposed health claims. FDA had rejected the claims on grounds that the substantiation did not meet the agency's "significant scientific agreement" standard. On appeal, the agency additionally argued that qualified claims or disclaimers were not permissible because they would unduly confuse consumers. The court rejected FDA's decision, holding that the agency's interest in promoting health was valid, but that it had violated the First Amendment in concluding that repression of the claims was preferable to disclosure with necessary qualifying information. The court thus sent the issue back to FDA for further consideration of whether qualified claims or disclaimers could be used to ensure truthful and non-misleading speech.

Finally, in Washington Legal Foundation v. Friedman, 13 F. Supp.2d 51 (D.D.C. 1998), the U.S. District Court for the District of Columbia ruled that FDA's restrictions on dissemination of third party literature on off-label uses of drug products constituted a violation of the First Amendment. Although the court recognized FDA's legitimate interest in restricting certain promotional speech by drug manufacturers, it found that the guidance documents at issue were unduly restrictive and, therefore, incompatible with the First Amendment.

3. FDA Should Modify Its Positions on Structure/Function Claims and Veterinary Medical Foods to Make Them Consistent with Recent Case Law

A. FDA Should Permit a Broader Range of Structure/Function Claims on Pet Foods

In its May 16, 2002 Notice, FDA acknowledges the tension between legitimate claims about the effect of an ingredient on the structure or function of the body ("structure/function claim") and drug claims and specifically asks what type of restrictions are appropriate for conventional foods.

CVM's restriction follows the approach used by FDA's Center for Food Safety and Applied Nutrition ("CFSAN") and arguably stems from the Federal Food Drug and Cosmetic Act ("FFDCA") definition of drug as "articles (other than food) intended to affect the structure or any function of the body of many or other animals." 21 U.S.C. § 321(g)(1)(C) (emphasis added). The parenthetical carve out indicates that under the FFDCA foods may be positioned to affect the structure or any function of the body of man or other animals without being categorized as drugs.

Statutorily, the scope of the carve out is limited only by the definition of food. Food is defined in the FFDCA as "articles used for food or drink for man or other animals . . . and articles used for components of any such article." 21 U.S.C. § 321(f)(1)(emphasis added). The definition of food makes clear that the carve out applies to both human and animal foods. However, because of the circularity of this definition, FDA has opted to look for further guidance to a non-statutory interpretation of the FFDCA food definition, which was articulated in Nutrilab v. Schweiker, 713 F.2d 335 (7th Cir. 1983). That interpretation states that: "substances used for food are those consumed either for taste, aroma, or nutritive value." FDA's CFSAN has used this reading of the statute to limit structure/function claims on foods to those that provide "nutritive value."

In keeping with this approach, CVM has informally articulated a policy of permitting structure/function claims on foods for animal use as long as those claims relate to a nutrient or "nutritive value": "If a food affects the structure or function of the body, it does so by these properties [nutritive value] (for example, a food may provide nutrients such as calcium for proper bone structure, or taurine for health heart function in cats)." "Interpreting Pet Food Labels – Special Use Foods," Information for Consumers, CVM, <www.fda.gov/cvm/index/consumer/labelint.htm>.

CVM explicitly rejects the possibility of such claims being permitted for non-classical nutrients or new ingredients: "if a product affects the structure or function of the body apart from its nutritive value, such as urine acidification or improvement in joint function, it may be considered a drug." "Interpreting Pet Food Labels – Special Use Foods," Information for Consumers, CVM, <www.fda.gov/cvm/index/consumer/labelint.htm>.

The CVM position was further articulated in a speech by Stephen Sundlof, Director of CVM, who stated that a claim such as "support proper joint cartilage development" for the ingredient glucosamine is a drug claim because scientific literature does not show that glucosamine is a required nutrient. Dr. Stephen Sundlof, Director, CVM, FDA, Speech Presented at the Pet Food Institute's 41st Annual Industry Meeting, Chicago, Illinois (Oct 26, 1998).

In support of this approach, CVM has articulated no justification other than a repetition of the Nutrilab definition of food. CVM's statements imply that the restriction is based on the government's interest in protecting pet health. However, this position is contradicted by the fact that CFSAN itself has been more flexible in its definition of "nutritive value" in recent years to include arguably non-nutritive substances.[3] CFSAN's shift began in early 1999 when FDA permitted

[3] In the January 6, 2000 regulation, "Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body," which clarified the breadth of structure/function claims for dietary supplements, FDA's CFSAN noted that the same range of structure/function claims would be available for human foods as long as the ingredients met relevant safety standards and had "nutritive value." The definition of "nutritive value" was not elaborated upon in that document. 65 Fed. Reg. 1034.

structure/function claims for new phytosterol ingredients added to margarines. These phytosterols were added solely for cholesterol-lowering/maintenance purposes, and thus do not fit FDA's traditional conception of nutritive value. Despite this lack of "fit," the agency permitted manufacturers to make structure/function claims about sterols and stanols.

CVM's policy on structure/function claims for pet foods thus does not satisfy the Central Hudson test. An imputed government interest in protecting pet health does not reasonably fit the agency's restriction on communicating truthful information about pet food ingredients. This government interest is also undermined by the fact that CFSAN has already begun permitting truthful and non-misleading structure/function claims about a broader range of ingredients in human foods. FDA's aim of ensuring pet health is better pursued under FDA's existing regulations, which require that food ingredients are safe for their intended use.

Ultimately, CVM's approach to structure/function claims interferes with the communication of beneficial health information to pet owners. In light of this analysis, Hill's asks that FDA modify its position on claims for animal foods so that any safe ingredient may be the subject of a structure/function claim on a pet food, provided the company has adequate substantiation.[4] Such an approach would support the dissemination of accurate and non-misleading information without risking pet health.

B. FDA Should Permit Manufacturers to Communicate Benefits of Veterinary Medical Foods Directly to Pet Owners

Hill's also believes that FDA should take this opportunity to revise its approach to Veterinary Medical Foods ("VMF"). CVM recognizes the value of this category, which includes food products intended for the nutritional support of disease used under the supervision of a veterinarian. William J. Burkholder, "The View From the Center for Veterinary Medicine," Pet Food Forum, 2002. However, as currently applied, CVM's policies impede the ability of pet food companies to communicate the benefits of such products directly to pet owners.

In CVM's interpretation, VMF are a subcategory of foods for animals that bear characteristics of both the better defined food and drug categories. Medical foods for human use were defined by the Orphan Drug Amendments of 1988. According to the statute, a medical food is:

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[4] In evaluating whether substantiation is adequate, FDA can look to standards articulated by the Federal Trade Commission ("FTC") or the National Advertising Division of the Better Business Bureau ("NAD") which have both addressed this issue. See Ralston-Purina, 720 F.Supp. 194 (D.D.C. 1989)(finding that research must be sufficiently reliable to permit tests to serve as the basis of pet food claims) and IAMS Active Maturity Pet Food (NAD Case # 3817, September 29, 2001)(applying a reasonable basis analysis to determine whether studies support pet food claim).

> a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. 21 U.S.C. § 360ee(b).

On November 29, 1996, FDA published an Advanced Notice of Proposed Rulemaking ("ANPR"), seeking comments on how to provide further regulation of medical foods for human use, in part because of the "rapid increase in the variety and number of products marketed as medical foods." 61 Fed. Reg. 60661. FDA has not issued any subsequent proposed rule or regulation. However, in the food context, the agency has allowed a number of products to go to market as long as the products are not represented as treating disease states.

CVM has acknowledged a medical foods category for animals that is analogous to the medical foods category for humans. In this context, CVM has stated that it "recognizes that VMF can have a scientific, physiological basis, and could serve a beneficial purpose if used correctly." William J. Burkholder, "The View From the Center for Veterinary Medicine," Pet Food Forum, 2002. According to CVM, three conditions must be met to be marketed as a VMF. First, the product must be sold by and used under the direction of a veterinarian. Second, overt drug claims are not allowed to appear on the label. And third, the products themselves must be composed of safe ingredients. Id. Together these requirements mean that facts about VMF may only be communicated in non-labeling format and through a veterinarian.

Given this regulatory approach, industry has not been able to fully utilize the VMF category in helping pet owners maximize pet health. Pet owners may only receive valuable information about VMF products upon visiting a veterinarian and thus have limited access to information about scientifically established effects that nutritional products may have on sick pets.

This approach negatively impacts pet health and unduly restricts truthful and non-misleading speech. Only a small percentage of pet owners obtain treatment for animals for the major animal diseases and sometimes these treatments are delayed because pet owners fail to recognize disease symptoms.

For example, the progressive and ultimately fatal disorder, chronic renal disease is often left untreated by pet owners because they do not recognize the signs of the disorder and are not aware that nutritional intervention can delay the onset of uremic crisis. Pets frequently develop kidney problems with advancing age. In a survey of 1,600 dogs over five years of age approximately 20% had abnormally elevated kidney function tests,[5] and another survey indicated that kidney disease

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[5] Leibetseder J. and Neufeld K., "Dietary Management Recommendations For Dogs With Chronic Renal Failure," Wiener Tierarztliche Monatsschrift 1992, 79:

was one of the top three causes of death for both dogs and cats.[6] Pet food designed to meet the nutritional needs of these pets can have a positive impact on the disease trajectory.

Despite the compelling evidence, this information is not presently available directly to consumers because of FDA's restriction on label information for VMF. As such, a large portion of pet owners are effectively cut off from information about the treatment.

FDA justifies its bar on direct to consumer labeling of VMF by stating "[a]n owner who feeds a VMF product for its desired therapeutic effect solely on the basis of labeling or advertising claims may cause harm resulting from improper diagnosis or treatment." David A. Dzanis, "Interpreting Pet Food Labels – Special Food Uses," CVM, www.fda.gov/cvm/index/consumer/labelint.htm. FDA further states that "as food, VMF are subject to the same labeling requirements as any other pet food. As such, labels may not bear drug claims." Id. However, CVM's position restricts companies from even mentioning disease and thus goes beyond what would be required to enforce the drug definition contained in 21 U.S.C. §321(g). As such, CVM's policy on VMF does not meet the first prong of the Central Hudson analysis, and certainly does not balance the significant public health interest in supporting the health and sustaining the lives of the large number of pets in America.

C. FDA Should Allow Use Of Qualified Claims To Ensure Consumers Receive Truthful And Non-Misleading Information

As stated in Thompson v. Western States Medical Center, 535 U.S. ___, "[i]f the Government can achieve its interests in a manner that does not restrict commercial speech, or that restricts less speech, the Government must do so." Hill's takes the position that FDA could permit a greater flow of relevant health information to pet owners, and still protect consumers from potentially misleading information, by endorsing the use of qualifying language or disclaimers in certain circumstances.

FDA has already embraced this approach with respect to health claims on dietary supplements in the wake of the Pearson case. 164 F.3d 650. The Pearson court made clear that protecting the health, safety and welfare of citizens is a legitimate government interest. Pearson, 164 F.3d at 656 (citing Rubin v. Coors Brewing Co., 514 U.S. 476 (1995)). At the same time, the court held that the disclosure of relevant health information is favored over repression, and that the where necessary, disclaimers or qualifying language should be used to ensure truthful and non-misleading communication to consumers.[7] Id. at 656. In the Pearson context, the court rejected as "dubious" FDA's position that consumers

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284-288.

[6] Morris Animal Foundation, 1997 Animal Health Survey. March, 1998.

[7] FTC has also embraced the principle of qualified claims "[w]hen the disclosure of qualifying information is necessary to prevent an ad from being deceptive." FTC, Dietary Supplements: An Advertising Guide For Industry," 1999.

would be confused by qualifying language on a product label, suggesting that this position reflects a "simplistic view of human nature." Id. at 656.

FDA implemented this decision by outlining circumstances in which, despite the lack of "significant scientific agreement" on a proposed claim, a health claim would be allowed with appropriate qualifying language. 65 Fed. Reg. 59855 (2000). Thus, FDA permits dietary supplements to bear *qualified* health claims if "the scientific evidence in support of the claim outweighs the scientific evidence against the claim." Id. at 59856. For example, dietary supplements may carry a health claim about the relationship between omega-3 fatty acids and Coronary Heart Disease, although proof of this relationship does not meet FDA standard, as long as appropriate qualifying language[8] is used. "Letter Clarifying Conditions for a Dietary Supplement Health Claim for Omega-3 Fatty Acids and Coronary Heart Disease," FDA, February 16, 2001.

Hill's believes that the same approach should be applied to claims on pet foods. FDA currently justifies its restrictions on the use of pet food claims with concerns about consumers receiving truthful and non-misleading information. In light of Pearson, this justification is not *per se* adequate to justify restrictions. Instead, Pearson makes clear that FDA is obliged to promote pet health while taking the steps necessary to ensure that consumers are not misled. Toward this end, Hill's urges FDA to adopt a policy of judicious use of qualifying language for both structure/function claims and claims on VMF labels.

4. Conclusion

The First Amendment and recent judicial decisions require FDA to be less restrictive of structure/function claims on pet foods and claims for VMF so that truthful, non-misleading information regarding these products can be communicated to pet owners. Thus, Hill's urges FDA to permit the use of qualifying language on pet food claims to facilitate the flow of information to the consumer.

Thank you for your consideration.

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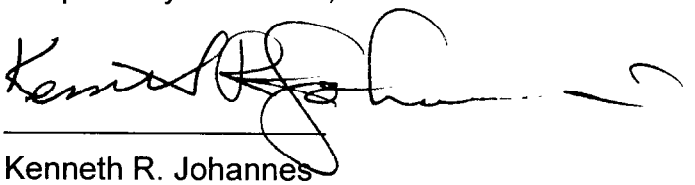
[8] FDA's suggested qualifying language in this context is: "The scientific evidence about whether omega-3 fatty acids may reduce the risk of coronary heart disease (CHD) is suggestive, but not conclusive. Studies in the general population have looked at diets containing fish and it is not known whether diets or omega-3 fatty acids in fish may have a possible effect on reduced risk of CHD. It is not known what effect omega-3 fatty acids may or may not have on risk of CHD in the general population."

Respectfully submitted,



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